



Billing Code 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; The Genetic Testing Registry

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Dina Paltoo, Director, Scientific Data Sharing Policy Division, Office of Science Policy, NIH, 6705 Rockledge Dr., Suite 750, Bethesda, MD 20892, or call non-toll-free number (301) 496-9838, or E-mail your request, including your address to: SciencePolicy@mail.nih.gov.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the Federal Register on April 2, 2018, page 14018 (83 FR 14018) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The Office of the Director (OD), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: The Genetic Testing Registry, 0925-0651, Expiration Date 07/31/2018—EXTENSION, Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: Clinical laboratory tests are available for more than 10,000 genetic conditions. The Genetic Testing Registry (GTR) provides a centralized, online location for test developers, manufacturers, and researchers to voluntarily submit detailed information about the availability and scientific basis of their genetic tests. The GTR is of value to clinicians by providing information about the accuracy, validity, and usefulness of genetic tests. The GTR also highlights evidence gaps where additional research is needed.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 4,198.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Time per Response (in hours)	Total Annual Burden Hour
Laboratory Personnel Using Bulk Submission	Minimal Fields	313	25	18/60	2,348
	Optional Fields	313	25	6/60	783
Laboratory Personnel Not Using Bulk Submission	Minimal Fields	64	25	30/60	800
	Optional Fields	64	25	10/60	267
TOTAL		377	18,850		4198

Dated: June 28, 2018.

Lawrence A. Tabak,

Principal Deputy Director,

National Institutes of Health.

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